K112758

510 (k) Summary

FEB 2 3 2012

This summary of safety and effectiveness information is being provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is:

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Submitter's Information:

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Date the Summary was Prepared: June 01, 2011

Device name:

- **Common Name:**

Endosseous Dental Implant, Root-form; Endosseous Dental Implant Abutment

- **Trade Name:**

One-Piece Implants 2.5x10, 2.5x12, 2.5x14; One-Piece Implants 3.0x10, 3.0x12, 3.0x14; KAT Implants System Implants 2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10; Angled Abutments 4.2 20°, 4.6 20°, 5.4 20°, 4.2 10°, 4.6 10°, 5.4 10°; Ball Abutments 3.5, 4.5, 5.5, 3.5 10°, 4.5 10°, 3.5 20°, 4.5 20°.

Classification name:

Endosseous Dental Implant (21 CFR 872.3640, Product code DZE)

- **Classification Panel:**

Dental

Device classification: Class II

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Indications for Use:

KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges.

KAT Implants System 2.5mm implants are self-tapping titanium alloy threaded screws indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT Implants System 2.5mm implants may also be used for inter-radicular transitional application.

KAT Implants System 3.0mm implants are indicated for use in maxillary lateral or mandibular lateral and central incisors in single or multiple units to support prosthesis, such as artificial teeth. The implant can be placed in extraction sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate.

KAT Implants System Abutments are intended to be used with KAT Implants System Dental Implants aid in prosthetic rehabilitation of the edentulous areas in maxilla and mandible.

The legally marketed devices to which the equivalence is claimed [807.92(a)(3)]:

KAT Implants System Implants 2.5, 3.0, 3.5, 4.3 and 5.0 mm diameters

Applicant: KAT Implants, LLC

510(k): K083544

KAT Implants System Implants 6.0, 7.0 and 8.0 mm diameters

Applicant: KAT Implants, LLC

510(k): K101201

KAT Implants System Straight Abutments 4.2x6.5, 4.6x6.5 and 5.4x6.5

Applicant: KAT Implants, LLC

510(k): K101201

KAT Implants System Implant Abutment 4.2x6.5

Applicant: KAT Implants, LLC

510(k): K083544

IMTEC Sendax MDI 1.8mm

Applicant: IMTEC Corporation (USA)

510(k) Number: K031106

Maximus 3.0mm Diameter Implant

Applicant: Biohorizons Implant Systems, Inc.

510(k) Number: K032351

O-ring Abutment

Applicant: Biohorizons Implant Systems, Inc.

510(k) Number: K99027

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Description of Devices:

Like the predicate KAT Implants System Implants 2.5mm and 3.0mm KAT Implants System One-piece implants 2.5mm and 3.0mm display the following characteristics: a) have a threaded body and a tapered post with an internal threaded bore, b) have the same indications, c) are manufactured from the same material (Ti6Al4V ELI alloy), c) have the same diameters (2.5 and 3.0mm) and implant body lengths (10, 12 and 14mm), d) are packaged with the same materials and undergo the same sterilization process. KAT Implants System One-piece implants 2.5mm and 3.0mm implants are not designed to receive any abutments; they are designed to receive the crowns directly via cementation procedure. KAT Implants System One-piece implants are blasted with a soluble tricalcium phosphate blasting media. All materials and manufacturing processes are the same for all KAT Implants System Dental Implants. The fatigue testing was executed per ISO 14801:2007, Dentisty – Implants - Dynamic fatigue testing on endosseous dental implants on a 4.2mm width by 8.5mm length abutment with 20 ° angularity and a 3.0mm diameter implant, which is considered worst-case representation for KAT Implants System implants having 3.0mm or greater diameter. In view of a fatigue test results (samples were able to withstand 440 N of force over 5 million cycles) and considering the fact that KAT Implants System One-piece Implants 3.0 and predicate KAT Implants System 3.0mm implants (K083544) have identical dimensions, no further fatigue testing was deemed necessary.

Predicate one-piece implant devices (IMTEC Sedax MDI 1.8mm and Maximus 3.0mm Diameter Implant) are the same as One-piece implants 2.5 and 3.0 in respect to material composition, surface treatment, diameters and lengths (for the exception of One-piece implant 3.0 x 10). Predicate Maximus 3.0mm Diameter Implant is not provided in 10 mm length, but another predicate - KAT 3.0mm implant cleared under K083544 is provided in 10 mm length.

Since predicate KAT Implants System 2.5mm implants (K083544) are approved for use with abutments of KAT Implants System, and considering the fact that KAT Implants System One-piece Implants 2.5 and predicate KAT Implants System 2.5mm implants (K083544) have identical dimensions, no further fatigue testing was deemed necessary.

KAT Implants System Angled Abutments are implant abutment devices intended to be distributed as part of the KAT Implants System. KAT Implants System currently consists of implants, abutments, and Class I accessory instrumentation cleared for marketing under Traditional 510(k) Pre-marketing Notification # K083544 and K101201. All dental abutments of the KAT Implants System are a) used for the same indication, b) are manufactured with the same Ti-6Al-4Va ELI alloy, c) undergo the same surface treatment and sterilization, d) packaged and labeled using the same packaging materials and Instructions for Use, and e) are intended to be assembled together during surgery utilizing the same locking-taper implant post/abutment connection, with the aid of the same KAT Implants System Class 1 accessories and instruments.

Like the predicate KAT Implants System Straight (Prepable) Abutments with outside diameters 4.2mm, 4.6mm and 5.4mm (all available only in 6.5mm length), KAT Implants System Angled Abutments which are subject of this 510(k), consist of a same-dimension internal hollow bore on one end for connection with the abutment-receiving post of the KAT Implants System Dental Implants. Like the abutment predicate, they are similarly designed to be retained by the KAT Implants System Dental Implants through the abutment-receiving post. A locking-taper connection is activated with a torque wrench set at 25 Ncm.

KAT Implants System Ball Abutments are implant abutment devices intended to be distributed as part of the KAT Implants System.

Like the predicate KAT Implants System Straight (Prepable) Abutments with outside diameters 4.2mm, 4.6mm and 5.4mm (all available only in 6.5mm length), KAT Implants System Ball

Abutments which are subject of this 510(k), consist of a same-dimension internal hollow bore on one end for connection with the abutment-receiving post of the KAT Implants System Dental Implants. Like the abutment predicate, they are similarly designed to be retained by the KAT Implants System Dental Implants through the abutment-receiving post. A locking-taper connection is activated with a tapping force – the same method used to activate locking taper connection on the other predicate - KAT Implants System Implant Abutment 4.2x6.5.

The material of construction (Ti-6Al-4Va ELI Alloy), all surface preparation, all packaging, labeling and sterilization of KAT Implants System Angled Abutments and Ball Abutments are the same as previously cleared KAT Implants Straight and Implant Abutments. The outside diameters are the same, however, dimensional characteristics which differ from KAT Implant System Straight Abutments predicate duly noted below:

Angled Abutments: outside diameter availability in 4.6mm, and 5.4mm (within the range of previously cleared KAT Implant System Straight Abutments outside diameters), all with an 8.5mm length at 10° and 20° angulation. Mesial-distal width of Angled Abutment 4.2 10° and Angled Abutment 4.2 20° is 4.2mm.

Ball Abutments: outside diameter availability in 4.2mm (within the range of previously cleared KAT Implant System Straight Abutments outside diameters), and lengths between 6.5 and 8.5mm at 0°, 10° and 20° angulation.

The dimensional properties arising from differences in length between KAT Implants System Angled and Ball Abutments and the predicate KAT Implants System Straight Abutments were investigated by fatigue testing on KAT Implants System Angled Abutment 4.2mm x 8.5mm (20 ° angularity) samples. The testing was executed per ISO 14801:2007, Dentistry – Implants - Dynamic fatigue testing on endosseous dental implants. The use of a 4.2mm width by 8.5mm length Angled Abutment with 20° angularity is considered worst-case scenario representation for KAT Implants System abutments.

All KAT Implants System Dental Implant and Abutment devices which are subject of this 510(k) and the listed predicate devices are substantially equivalent because they are:

Manufactured using the same Titanium-6Aluminum-4Vanadium ELI alloy (certified to meet ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications and biocompatibility requirements of Class II Special Control Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments);

Packaged with the same size and material primary packaging (in conformance with material and process requirements of ISO 11607, Packaging for Terminally-Sterilized Medical Devices and ASTM F88, Standard Test Method for Seal Strength of Flexible Barrier Materials);

Are sterilized using the same sterilization process and sterility assurance level with SAL = 10-6 (per ISO 11137, Sterilization of Healthcare Products – Radiation).

Have the same Indications for Use.

Do not present any new dimensions and operating technology from endosseous dental implants and abutments already present in the market.

The only modifications that were made are:

1. Angle of the predicate Straight Abutments was changed from 0° to 10° and 20°;

2. Length of the predicate Straight Abutments was changed from 6.5mm to longer lengths. New abutment devices were named Angled Abutments 4.2 20°, 4.6 20°, 5.4 20°, 4.2 10°, 4.6 10°, 5.4 10°.

3. Internal thread of the Straight Abutments was removed and a ball element was added. New abutment devices were named Ball Abutments 3.5, 4.5, 5.5, 3.5 10°, 4.5 10°, 3.5 20°, 4.5 20°.

4. Abutment receiving post of the predicate KAT Implants System Implants 2.5 and 3.0 was made longer. New implant devices were named One-Piece Implants 2.5 and 3.0;

5. Implant blasting media was changed from aluminum oxide to a soluble tricalcium phosphate. All KAT Implants System Implants will be blasted with soluble tricalcium phosphate and will retain original names.

Summary of similarities and modifications between the devices which are subject of this 510(k) and predicate device is presented in the table below.

Areas of Comparison	KAT Implants System Dental Implants	KAT Implants System Implants blasted with a soluble tricalcium phosphate media	KAT Implants System One-Piece Implants	IMTEC Sendax MDI 1.8mm	Maximus 3.0mm	KAT Implants System Angled Abutments 10° and 20°	KAT Implants System Straight (Prepable) Abutments	KAT Implants System Implant Abutment 4.2x6.5	KAT Implants System Ball Abutments	O-ring Abutment
Regulatory Status	***Predicate***	*Present submission*	*Present submission*	***Predicate***	***Predicate***	*Present submission*	***Predicate***	***Predicate***	*Present submission*	***Predicate***
510(k) number	***K083544 and K101201***	*Present submission*	*Present submission*	***K031106***	***K032351***	*Present submission*	***K101201***	***K083544***	*Present submission*	***K99027***
Intended Use	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant	Dental Abutment	Dental Abutment	Dental Abutment	Dental Abutment	Dental Abutment
Device Nominal Dimensions (Diameter x Length) in mm	2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10	2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10	2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14	1.8x10, 1.8x12, 1.8x14	3.0x12, 3.0x15, 3.0x18	4.2x8.5, 4.6x8.5, 5.4x8.5	4.2x6.5, 4.6x6.5, 5.4x6.5	4.2x6.5	4.2x6.5, 4.2x7.5, 4.2x8.5	4.5, 6.5, 8.5 length provided in 3.5, 4.5 and 5.7 mm diameters
Device	N/A	N/A	N/A	N/A	N/A	10° and 20°	0°	0°	0°, 10° and 20°	0°

K112788

Angulation										
Indications for Use	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. KAT Implants System 2.5mm implants are	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. KAT Implants System 2.5mm implants are self-tapping titanium alloy threaded screws	The MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional application. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial edentulism, and employing minimally invasive surgical intervention.	The BioHorizons 3.0mm diameter implant may be used: (1) as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implant may be immediately restored with a temporary prosthesis that is not in functional occlusion; (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges.	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges.	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in	KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary	Biohorizons O-ring Abutment system is intended to provide a direct attachment for tissue supported retained by two or more implants with up to 10 degree divergence.

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	stability. KAT Implants System 2.5mm implants are self-tapping titanium alloy threaded screws indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT Implants System 2.5mm implants may also be used for inter-radicular transitional application. KAT Implants System 3.0mm implants are indicated for use in maxillary lateral or mandibular lateral and	self-tapping titanium alloy threaded screws indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT Implants System 2.5mm implants may also be used for inter-radicular transitional application. KAT Implants System 3.0mm implants are indicated for use in maxillary lateral or mandibular lateral and central incisors in single or multiple units	indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT Implants System 2.5mm implants may also be used for inter-radicular transitional application. KAT Implants System 3.0mm implants are indicated for use in maxillary lateral or mandibular lateral and central incisors in single or multiple units to support prosthesis, such as artificial teeth. The implant can be placed in extraction		incisors. The implants may be restored after a period of time or placed in immediate function; (3) for denture stabilization using multiple implants in the anterior mandible and maxilla. The implants may be restored after a period of time or placed in immediate function.	Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability. KAT Implants System Angled Abutments are not intended to be used with unsplinted 2.5mm diameter implants in posterior region.	Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	Type IV bone due to difficulty in achieving primary stability.	stability.	

K110758

	central incisors in single or multiple units to support prosthesis, such as artificial teeth. The implant can be placed in extraction sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving primary stability.	to support prosthesis, such as artificial teeth. The implant can be placed in extraction sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate.	sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate.							
Type of implant / abutment connection	1.5 ° press fit activated locking taper connection	1.5 ° press fit activated locking taper connection	N/A One-Piece Implant	N/A One-Piece Implant	N/A One-Piece Implant	1.5 ° press fit activated locking taper connection	1.5 ° press fit activated locking taper connection	1.5 ° press fit activated locking taper connection	1.5 ° press fit activated locking taper connection	Screw retained
Platform size	3.1mm diameter	3.1mm diameter	3.1mm diameter	2mm diameter	3.1mm diameter	3.1mm diameter	3.1mm diameter	3.1mm diameter	3.1mm diameter	3.5, 4.5 and 5.7 mm

K110253

	implant post	implant post	implant post	implant post	implant post	implant post	implant post	implant post	implant post	diameter
Mode of Abutment to mplant attachment	N/A	N/A	N/A	N/A	N/A	Torque application (25 Ncm)	Torque application (25 Ncm)	Torque application (25 Ncm) or tapping force	Tapping force	Screw retained
Associated Class I components	Implant placement/removal instrumentation	Implant placement/removal instrumentation	Implant placement/removal instrumentation	Implant placement/removal instrumentation	Implant placement/removal instrumentation	Abutment placement/removal instrumentation	Abutment placement/removal instrumentation	Abutment placement/removal instrumentation	Abutment placement/removal instrumentation and O-ring housing with EPDM rubber O-ring	Placement instrumentation and O-ring housing with Silicon O-ring
Type of mplant	Endosseous screw type with a continuous thread and horizontal circumferential fins.	Endosseous screw type with a continuous thread and horizontal circumferential fins.	Endosseous screw type with a continuous thread and horizontal circumferential fins.	Endosseous screw type with a continuous thread	Endosseous screw type with a continuous thread	N/A	Endosseous screw type with a continuous thread and horizontal circumferential fins.	N/A	N/A	N/A
Materials used	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI	Titanium alloy Ti6Al4V ELI
Biocompatibility	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	N/A	N/A	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	Titanium alloy Ti6Al4V ELI is used for manufacturing of all implants and abutments of KAT Implants System	N/A
Blasting media	100 micron Aluminum Oxide	<300 grit soluble tricalcium phosphate	<300 grit soluble tricalcium phosphate	Aluminum oxide	<300 grit soluble tricalcium phosphate	N/A	N/A	N/A	N/A	N/A

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Mechanical Safety	Fatigue testing was performed on a 3.0mm diameter implant and a 8.5mm long 20° angle abutment according to ISO 14801:2007	Fatigue testing was performed on a 3.0mm diameter implant and a 8.5mm long 20° angle abutment according to ISO 14801:2007	Fatigue testing was performed on a 3.0mm diameter implant and a 8.5mm long 20° angle abutment according to ISO 14801:2007	Unknown	Unknown	Fatigue testing was performed on a 3.0mm diameter implant and a 8.5mm long 20° angle abutment according to ISO 14801:2007	Fatigue testing was performed on a 3.5mm diameter implant and a 6.5mm long implant abutment as part of K083544	Fatigue testing was performed on a 3.5mm diameter implant and a 6.5mm long implant abutment as part of K083544	Fatigue testing was performed on a 3.0mm diameter implant and a 8.5mm long 20° angle abutment according to ISO 14801:2007	Unknown

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Summary of the non-clinical test submitted as part of this submission:

The fatigue testing was executed per ISO 14801:2007, *Dentisty – Implants - Dynamic fatigue testing on endosseous dental implants* on a 4.2mm width by 8.5mm length abutment with 20° angularity and a 3.0mm diameter implant. See Attachment 4 - "KAT Implants Fatigue Test".

Ball Abutment Rotational Stability Test was conducted to justify the use of a tapping force to seat ball abutments. See Attachment 5 – "Ball Abutment Rotational Stability Test".

Conclusions Drawn:

The following devices listed in this pre-marketing notification:

One-Piece Implants 2.5x10, 2.5x12, 2.5x14; One-Piece Implants 3.0x10, 3.0x12, 3.0x14; KAT Implants System Implants 2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10; Angled Abutments 4.2 20°, 4.6 20°, 5.4 20°, 4.2 10°, 4.6 10°, 5.4 10°; Ball Abutments 3.5, 4.5, 5.5, 3.5 10°, 4.5 10°, 3.5 20°, 4.5 20°.

are substantially equivalent to the noted predicate devices based on tabulated device specifications and properties presented in the Summary of Technological Characteristics. These proposed devices are substantially equivalent to the predicate devices because they have:

- same fundamental scientific technology and intended use as the predicate device;
- same materials, processing, packaging, sterilization and inspection methods;
- same manufacturing infrastructures (both human and physical);
- same instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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FEB 2 3 2012

Re: K112758
Trade/Device Name: One-Piece Implants 2.5x10, 2.5x12, 2.5x14; One-Piece Implants 3.0x10, 3.0x12, 3.0x14; KAT Implants System Implants 2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10; Angled Abutments 4.2 20°, 4.6 20°, 5.4 20°, 4.2 10°, 4.6 10°, 5.4 10°; Ball Abutments 3.5, 4.5, 5.5, 3.5 10°, 4.5 10°, 3.5 20°, 4.5 20°.
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 15, 2012
Received: February 15, 2012

Dear Dr. Bondar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112758

Indications for Use Statement

510(k) Number (if known) _____

Device Name

One-Piece Implants 2.5x10, 2.5x12, 2.5x14; One-Piece Implants 3.0x10, 3.0x12, 3.0x14; KAT Implants System Implants 2.5x10, 2.5x12, 2.5x14, 3.0x10, 3.0x12, 3.0x14, 3.5x8, 3.5x10, 3.5x12, 3.5x14, 4.3x6, 4.3x8, 4.3x10, 4.3x12, 4.3x14, 5.0x6, 5.0x8, 5.0x10, 5.0x12, 5.0x14, 6.0x6, 6.0x8, 6.0x10, 7.0x6, 7.0x8, 7.0x10, 8.0x6, 8.0x8, 8.0x10; Angled Abutments 4.2 20°, 4.6 20°, 5.4 20°, 4.2 10°, 4.6 10°, 5.4 10°; Ball Abutments 3.5, 4.5, 5.5, 3.5 10°, 4.5 10°, 3.5 20°, 4.5 20°.

Indications for Use

KAT Implants System is intended to restore edentulous areas of maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implant can be placed in extraction sites or healed alveolar ridges.

KAT Implants System 2.5mm implants are self-tapping titanium alloy threaded screws indicated for transitional and long-term intra-bony applications, such as providing support for transitional or long term crowns, bridges and dentures. KAT Implants System 2.5mm implants may also be used for inter-radicular transitional application.

KAT Implants System 3.0mm implants are indicated for use in maxillary lateral or mandibular lateral and central incisors in single or multiple units to support prosthesis, such as artificial teeth. The implant can be placed in extraction sites or healed alveolar ridges and can be immediately loaded when good primary stability is achieved and the functional load is appropriate.

KAT Implants System Abutments are intended to be used with KAT Implants System Dental Implants aid in prosthetic rehabilitation of the edentulous areas in maxilla and mandible.

Prescription Use __x__ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112758